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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Senn Chemicals AG, Guido Senn-Strasse 1, 8157 Dielsdorf,** Authorisation No. 511891-102700716 with its site **Senn Chemicals AG, Industriestrasse 12, 8157 Dielsdorf, Switzerland,** Site No. 1000739 has been duly authorised to perform the manufacturing activities according to the table below;

that the company is keeping the required level for Good Manufacturing Practices for Medicinal Products (GMP) according to the Swiss regulations in force. These regulations are in accordance with the requirements for good practices in the manufacture and quality control of the Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S) as well as with The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union/Canada and Switzerland;

that the manufacturing plant of the company is subject to official periodic inspections; the last regular inspection was conducted on **26.08.2022** (dd.mm.yyyy).

No.	*Operation*	*Scope**
3	**MANUFACTURE OF ACTIVE SUBSTANCES**	
3.1	**Manufacture of active substance by chemical synthesis**	
3.1.1	Manufacture of active substance intermediates	H/V, I
3.1.2	Manufacture of crude active substance	H/V, I
3.1.3	Salt formation / Purification steps: crystallization	H/V, I
3.5	**General finishing steps**	
3.5.1	Physical processing steps: Miling	H/V, I
3.5.2	Primary packaging	H/V, I
3.5.3	Secondary packaging	H/V, I
3.5.4	Other: Lyophylisation	H/V, I
3.6	**Quality control testing**	
3.6.1	Physical / Chemical testing	H/V, I

* Scope of authorisation:

H/V	Human and veterinary medicinal products, without investigational products
V	Veterinary medicinal products only, without investigational products
I	Human investigational medicinal products
–	Not specified

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Berne, **12.06.2023** (dd.mm.yyyy)
No. GMP-CH-1004420

Swissmedic, Swiss Agency for Therapeutic Products

Marianne Baumann

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

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